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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/485,377	04/24/2000	KLAUS SOMMERMEYER	6-1037-001	1845

803 7590 06/15/2005

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EXAMINER

MAIER, LEIGH C

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/485,377	Applicant(s) SOMMERMEYER ET AL.	
	Examiner Leigh C. Maier	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 11, 2005 has been entered.

Claim 10 has been canceled. Claim 1 has been amended. Claims 1-9 and 11-22 are pending. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

The amendment filed March 11, 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure, is as follows: The amendment adds a new, previously undescribed, sub-set of starch derivatives, ones that are soluble in the aqueous hydrolysis solution. The original disclosure described particular soluble starch derivatives—hydroxyethyl, hydroxypropyl, and partially hydrolyzed starch—but it does not describe the sub-genus of “any starch derivative that is soluble in an aqueous hydrolysis solution.”

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112 – 1st paragraph

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that Applicant, at the time the application was filed, had possession of the claimed invention.

Upon further consideration of what limitations are and are not supported in the original specification, see discussion above, it is found that the amendment to claim 1 (submitted July 12, 2004) adds a limitation that is not supported by the original specification. The amendment adds that limitation “starch to be hydrolyzed that is soluble in the aqueous hydrolysis medium.” As discussed above, the specification describes particular soluble derivatives, but not this sub-genus of any and all soluble starch derivatives.

It is further noted that the most recent amendment to claim 1 also contains a limitation that is not supported in the specification. The claim has been amended to a “method for the continuous production of a plasma diluent or dialysis solutions ... wherein the plasma diluent or dialysis solutions have a molecular weight ranging from about 60,000 to 600,000.” This molecular weight range is not described in the specification, as filed. Applicant notes that “EP-A1 0 402 724 is mentioned which discloses the breakdown of hydroxyethyl starch ... [comprising] a mean molecular weight of 60,000 to 600,000.” However, the mere mention of a patent or other document is not a proper incorporation-by-reference, so the material contained therein is not available for the support of claim limitations.

Claim Rejections - 35 USC § 103

Claims 1-8 and 10-22 are again rejected under 35 U.S.C. 103(a) as being unpatentable over SOMMERMEYER et al (US 5,218,108) in combination with KOMAI et al (US 3,446,664), as set forth in the previous Office action.

Claim 1 has been amended to add limitations regarding flow rate and molecular weights of the final products.

SOMMERMEYER teaches as discussed previously. The reference further suggests that the molecular weight of the hydrolyzed/hydroxyethylated starch is about 60,000 to 6000,000. See abstract. The reference also exemplifies a product having molecular weight of 234,000. See col 5, lines 18-20.

Regarding flow rates, KOMAI does not teach the flow rates recited in the claims. However, the reference teaches that it is desirable to have uniform flow across a section of the reactor tube. See col 4, lines 3-13. In order to do so, it would be necessary for the practitioner to optimize the flow rate to avoid mixing of the layers. Maintaining a uniform flow rate for a given cross section, by definition, avoids mixing of layers.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the process of KOMAI for the first hydrolysis process for preparing a plasma expander (diluent) as taught by SOMMERMEYER. It would be within the scope of the artisan to optimize the flow rate for the particular solution viscosity in order to maintain uniform flow rate across the reactor cross section. It would be further obvious using the process and teaching of SOMMERMEYER, to further process the starch in order to prepare a derivatized starch in the molecular weight range recited, as this is the range taught to have utility for this

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purpose. The attached chromatograms have been considered, but a smaller molecular weight distribution would be expected. See discussion in KOMAI, above.

Claims 1, 2, 4-7, 9-15, 17, and 19-22 are again rejected under 35 U.S.C. 103(a) as being unpatentable over SOMMERMEYER et al (US 5,218,108) in combination with KOMAI et al (US 3,446,664) in view of SMOLKA et al (US 4,562,086), as set forth in the previous Office action.

The new limitations to the claims are addressed above. Applicant has added no new arguments regarding SMOLKA.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached one Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (571) 272-0661, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-9306.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

Leigh C. Maier

Leigh C. Maier
Primary Examiner
June 13, 2005